General

Guideline Title

Clinical practice guideline: otitis media with effusion (update).

Bibliographic Source(s)

Rosenfeld RM, Shin JJ, Schwartz SR, Coggins R, Gagnon L, Hackell JM, Hoelting D, Hunter LL, Kummer AW, Payne SC, Poe DS, Veling M, Vila PM, Walsh SA, Corrigan MD. Clinical practice guideline: otitis media with effusion (update). Otolaryngol Head Neck Surg. 2016 Feb;154(1 Suppl):S1-S41. [212 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Academy of Family Physicians, American Academy of Otolaryngology-Head and Neck Surgery, American Academy of Pediatrics Subcommittee on Otitis Media with Effusion. Otitis media with effusion. Pediatrics. 2004 May;113(5):1412-29. [172 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The evidence grades (A-D, X) and evidence-based statements (Strong Recommendation, Recommendation, and Option) are defined at the end of the "Major Recommendations" field.

Statement 1a. Pneumatic Otoscopy

The clinician should document the presence of middle ear effusion with pneumatic otoscopy when diagnosing otitis media with effusion (OME) in a child.

Strong recommendation based on systematic review of diagnostic studies with a preponderance of benefit over harm.

Statement 1b. Pneumatic Otoscopy

The clinician should perform pneumatic otoscopy to assess for OME in a child with otalgia, hearing loss, or both.

Strong recommendation based on systematic review of diagnostic studies with a preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: To improve diagnostic accuracy for OME with a readily available but underutilized means of assessing middle ear status (National Quality Strategy domain: clinical process/effectiveness)
- Aggregate evidence quality: Grade A, systematic review of cross-sectional studies with a consistent reference standard
- Level of confidence in evidence: High
- Benefit: Improve diagnostic certainty; reduce false-negative diagnoses caused by effusions that do not have obvious air bubbles or an air-fluid level; reduce false-positive diagnoses that lead to unnecessary tests and costs; readily available equipment; document mobility of the tympanic membrane; efficient; cost-effective
- Risks, harms, costs: Costs of training clinicians in pneumatic otoscopy; false-positive diagnoses from nonintact tympanic membrane; minor procedural discomfort
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Pneumatic otoscopy is underutilized for diagnosing OME, especially in primary care settings; accurate diagnosis of OME using pneumatic otoscopy is a prerequisite for managing children with OME
- Intentional vagueness: None
- Role of patient preferences: Very limited
- Exceptions: None
- Policy level: Strong recommendation
- Differences of opinion: None

Statement 2. Tympanometry

Clinicians should obtain tympanometry in children with suspected OME for whom the diagnosis is uncertain after performing (or attempting) pneumatic otoscopy.

Strong recommendation based on extrapolation of systematic reviews of diagnostic studies with a preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: Improve diagnostic accuracy for OME and raise awareness regarding the value of tympanometry as an objective measure of middle ear status (National Quality Strategy domain: clinical process/effectiveness)
- Aggregate evidence quality: Grade B, extrapolation from systematic review of cross-sectional studies with a consistent reference standard for tympanometry as a primary diagnostic method
- Level of confidence in evidence: High regarding the value of tympanometry for primary diagnosis; medium regarding the value as an adjunct to pneumatic otoscopy
- Benefit: Improved diagnostic accuracy; confirm a suspected diagnosis of OME; obtain objective information regarding middle ear status; differentiate OME (normal equivalent ear canal volume) vs tympanic membrane perforation (high equivalent ear canal volume); obtain prognostic information on likelihood of timely spontaneous resolution (e.g., a flat, or type B, tracing has the poorest prognosis); educational value in confirming pneumatic otoscopy findings
- Risks, harms, costs: Cost; lack of access; equipment calibration and maintenance; misinterpretation of findings
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: The individual who performs tympanometry is not specified and could be the clinician or another health professional; whether to use portable or tabletop tympanometry is at the discretion of the clinician
- Role of patient preferences: Limited
- Exceptions: Patients with recent ear surgery or trauma
- Policy level: Strong recommendation
- Differences of opinion: None

Statement 3. Failed Newborn Hearing Screen

Clinicians should document in the medical record counseling of parents of infants with OME who fail a newborn hearing screen regarding the importance of follow-up to ensure that hearing is normal when OME resolves and to exclude an underlying sensorineural hearing loss (SNHL).

Recommendation based on observational studies with a predominance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: Increase adherence to follow-up and ensure that an underlying SNHL is not missed (National Quality Strategy domains: care coordination, patient and family engagement)
- Aggregate evidence quality: Grade C, indirect observational evidence on the benefits of longitudinal follow-up for effusions in newborn screening programs and the prevalence of SNHL in newborn screening failures with OME
- Level of confidence in evidence: Medium
- Benefit: More prompt diagnosis of SNHL; earlier intervention for hearing loss; reduce loss to follow-up; reassure parents
- Risks, harms, costs: Time spent in counseling; parental anxiety from increased focus on child hearing issues
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: The method and specifics of follow-up are at the discretion of the clinician but should seek resolution of OME within 3 months of onset or, if not known, diagnosis
- Role of patient preferences: Minimal role regarding the need for counseling but a large role for shared decision making in the specifics of how follow-up is implemented and in what specific care settings
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

Statement 4a. Identifying At-risk Children

Clinicians should determine if a child with OME is at increased risk for speech, language, or learning problems from middle ear effusion because of baseline sensory, physical, cognitive, or behavioral factors (see Table 3 in the original guideline document).

Recommendation based on observational studies with a preponderance of benefit over harm.

Statement 4b. Evaluating At-risk Children

Clinicians should evaluate at-risk children (see Table 3 in the original guideline document) for OME at the time of diagnosis of an at-risk condition and at 12 to 18 months of age (if diagnosed as being at risk prior to this time).

Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: Raise awareness of a subset of children with OME (see Table 3 in the original guideline document) who are disproportionately affected by middle ear effusion as compared with otherwise healthy children and to detect OME in at-risk children that might have been missed without explicit screening but could affect their developmental progress (National Quality Strategy domain: population/public health)
- Aggregate evidence quality: Grade C, observational studies regarding the high prevalence of OME in at-risk children and the known impact of hearing loss on child development; D, expert opinion on the ability of prompt diagnosis to alter outcomes
- Level of confidence in the evidence: Medium
- Benefit: Identify at-risk children who might benefit from early intervention for OME (including tympanostomy tubes) and from more active and accurate surveillance of middle ear status; identify unsuspected OME and reduce the impact of OME and associated hearing loss on child development
- Risks, harms, costs: Direct costs of evaluating for OME (e.g., tympanometry), identifying self-limited effusions, parental anxiety, potential for overtreatment
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: The guideline update group (GUG) assumed that at-risk children (see Table 3 in the original guideline document) are less likely to tolerate OME than would the otherwise healthy child and that persistent OME could limit the benefit of ongoing therapies and education interventions for at-risk children with special needs; assumption that early identification of OME in at-risk children could improve developmental outcomes
- Intentional vagueness: The method of evaluating for OME is not specified but should follow recommendations in this guideline regarding pneumatic otoscopy and tympanometry; an interval of 12 to 18 months is stated to give the clinician flexibility and to ensure that evaluation takes place at a critical time in the child's development
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

Statement 5. Screening Healthy Children

Clinicians should not routinely screen children for OME who are not at risk and do not have symptoms that may be attributable to OME, such as hearing difficulties, balance (vestibular) problems, poor school performance, behavioral problems, or ear discomfort.

Recommendation against based on randomized controlled trials (RCT) and cohort studies with a preponderance of harm over benefit.

Action Statement Profile

- Quality improvement opportunity: Avoid unnecessary tests and treatment for a highly prevalent and usually self-limited condition (National Quality Strategy domains: efficient use of health care resources, population/public health)
- Aggregate evidence quality: Grade A, systematic review of RCTs
- Level of confidence in the evidence: High
- Benefit: Avoid unnecessary tests, avoid unnecessary treatment, limit parent anxiety
- Risks, harms, costs: Potential to miss clinically relevant OME in some children
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Role of patient preferences: Limited but a parent can request screening if desired
- Intentional vagueness: The word "routine" is used to indicate that there may be specific circumstances where screening is appropriate—for example, a child with a strong family history of otitis media or a child who is suspected to be at risk but does not yet have a formal at-risk diagnosis
- Exceptions: None
- Policy level: Recommendation against
- Difference of opinions: None

Statement 6. Patient Education

Clinicians should educate families of children with OME regarding the natural history of OME, need for follow-up, and the possible sequelae.

Recommendation based on observational studies and preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: Provide clear, patient-friendly education regarding OME, its natural history, and possible sequelae to empower families for shared decisions (National Quality Strategy domain: patient and family engagement)
- Aggregate evidence quality: Grade C, observational studies
- Level of confidence in the evidence: High
- Benefits: Reduce anxiety; facilitate shared decisions; provide parents with a fuller understanding of their child's condition; emphasize the importance of follow-up; educate families about risk factors and coping strategies
- Risks, harms, costs: Time for education
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: Limited
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

Statement 7. Watchful Waiting

Clinicians should manage the child with OME who is not at risk with watchful waiting for 3 months from the date of effusion onset (if known) or 3 months from the date of diagnosis (if onset is unknown).

Strong recommendation based on systematic review of cohort studies and preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: Avoid interventions with potential adverse events and cost for a condition that is usually self-limited (National Quality Strategy domains: patient safety, efficient use of health care resources)

- Aggregate evidence quality: Grade A, systematic review of cohort studies
- Level of confidence in the evidence: High
- Benefit: Avoid unnecessary referrals, evaluations, and interventions; take advantage of favorable natural history
- Risks, harms, costs: Delays in therapy for OME that persists for >3 months, prolongation of hearing loss
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Importance of avoiding interventions in an often self-limited condition
- Intentional vagueness: None
- Role of patient preferences: Small
- Exceptions: At-risk children (see Table 3 in the original guideline document) who may be offered tympanostomy tubes earlier than 3 months if there is a type B tympanogram in one or both ears
- Policy level: Strong recommendation
- Differences of opinion: None

Statement 8a. Steroids

Clinicians should recommend against using intranasal steroids or systemic steroids for treating OME.

Strong recommendation against based on systematic review of RCTs and preponderance of harm over benefit.

Statement 8b. Antibiotics

Clinicians should recommend against using systemic antibiotics for treating OME.

Strong recommendation against based on systematic review of RCTs and preponderance of harm over benefit.

Statement 8c. Antihistamines or Decongestants

Clinicians should recommend against using antihistamines, decongestants, or both for treating OME.

Strong recommendation against based on systematic review of RCTs and preponderance of harm over benefit.

Action Statement Profile

- Quality improvement opportunity: Discourage medical therapy that does not affect long-term outcomes for OME (resolution, hearing levels [HLs], or need for tympanostomy tubes) but does have significant cost and potential adverse events (National Quality Strategy domain: patient safety, efficient use of health care resources).
- Aggregate evidence quality: Grade A, systematic review of well-designed RCTs
- Level of confidence in the evidence: High
- Benefit: Avoid side effects and reduce cost by not administering medications; avoid delays in definitive therapy caused by short-term improvement then relapse; avoid societal impact of inappropriate antibiotic prescribing on bacterial resistance and transmission of resistant pathogens
- Risks, harms, costs: None
- Benefit-harm assessment: Preponderance of benefit over harm (in recommending against therapy)
- Value judgments: Emphasis on long-term outcomes, based on high-quality systematic reviews, even though some therapies (e.g., antibiotics, systemic steroids) have documented short-term benefits
- Intentional vagueness: None
- Role of patient preferences: Small
- Exceptions: Patients in whom any of these medications are indicated for primary management of a coexisting condition with OME
- Policy level: Strong recommendation (against therapy)
- Differences of opinion: None

Statement 9. Hearing Test

Clinicians should obtain an age-appropriate hearing test if OME persists for ≥3 months OR for OME of any duration in an at-risk child.

Recommendation based on cohort studies and preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: Obtains objective information on hearing status that could influence counseling and management of OME

(National Quality Strategy domain: clinical process/effectiveness)
- Aggregate evidence quality: Grade C, systematic review of RCTs showing hearing loss in about 50% of children with OME and improved hearing after tympanostomy tube insertion; observational studies showing an impact of hearing loss associated with OME on children's auditory and language skills
- Level of confidence in the evidence: Medium
- Benefit: Detect unsuspected hearing loss; quantify the severity and laterality of hearing loss to assist in management and follow-up decisions; identify children who are candidates for tympanostomy tubes
- Risks, harms, costs: Access to audiology, cost of the audiology assessment
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Knowledge of hearing status is important for counseling and managing children with OME and optimizing their learning environment, even if this information does not determine surgical candidacy
- Intentional vagueness: The words *age-appropriate* audiologic testing are used to recognize that the specific methods will vary with the age of the child, but a full discussion of the specifics of testing is beyond the scope of this guideline
- Role of patient preferences: Small; caregivers may decline testing
- Exceptions: None
- Policy level: Recommendation
- Difference of opinion: None

Statement 10. Speech and Language

Clinicians should counsel families of children with bilateral OME and documented hearing loss about the potential impact on speech and language development.

Recommendation based on observational studies and preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: Raise awareness of the potential impact of hearing loss secondary to OME on a child's speech and language and facilitate caregiver education (National Quality Strategy domains: patient and family engagement, care coordination)
- Aggregate evidence quality: Grade C, observational studies; extrapolation of studies regarding the impact of permanent mild hearing loss on child speech and language
- Level of confidence in the evidence: Medium
- Benefit: Raise awareness among clinicians and caregivers; educate caregivers; identify and prioritize at-risk children for additional assessment
- Risks, harms, costs: Time spent in counseling
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Group consensus that there is likely an underappreciation of the impact of bilateral hearing loss secondary to OME on speech and language development
- Intentional vagueness: None
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Difference of opinion: None

Statement 11. Surveillance of Chronic OME

Clinicians should reevaluate, at 3- to 6-month intervals, children with chronic OME until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: Emphasize that regular follow-up is an important aspect of managing chronic OME that can help avoid sequelae by identifying children who develop signs or symptoms that would prompt intervention (National Quality Strategy domains: patient safety, clinical process/effectiveness)
- Aggregate evidence quality: Grade C, observational studies
- Level of confidence in the evidence: High

- Benefit: Detection of structural changes in the tympanic membrane that may require intervention; detection of new hearing difficulties or symptoms that would lead to reassessing the need for intervention, including tympanostomy tubes; discussion of strategies for optimizing the listening-learning environment for children with OME; as well as ongoing counseling and education of parents/caregiver
- Risks, harms, costs: Cost of follow-up
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Although it is uncommon, untreated OME can cause progressive changes in the tympanic membrane that require surgical intervention. There was an implicit assumption that surveillance and early detection/intervention could prevent complications and would provide opportunities for ongoing education and counseling of caregivers
- Intentional vagueness: The surveillance interval is broadly defined at 3 to 6 months to accommodate provider and patient preference; "significant" hearing loss is broadly defined as that noticed by the caregiver, reported by the child, or interfering with school performance or quality of life
- Role of patient preferences: Moderate; opportunity for shared decision making regarding the surveillance interval
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

Statement 12a. Surgery for Children <4 Years Old

Clinicians should recommend tympanostomy tubes when surgery is performed for OME in a child <4 years old; adenoidectomy should not be performed unless a distinct indication (e.g., nasal obstruction, chronic adenoiditis) exists other than OME.

Recommendation based on systematic reviews of RCTs with a preponderance of benefit over harm.

Statement 12b. Surgery for Children ≥4 Years Old

Clinicians should recommend tympanostomy tubes, adenoidectomy, or both when surgery is performed for OME in a child 4 years old or older.

Recommendation based on systematic reviews of RCTs and observational studies with a preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: Promote effective therapy for OME (tubes at all ages; adenoidectomy age ≥4 years) and discourage therapy with limited or no benefits (adenoidectomy <4 years old) (National Quality Strategy domains: patient safety, clinical process/effectiveness)
- Aggregate evidence quality: Grade B, systematic review of RCTs (tubes, adenoidectomy) and observational studies (adenoidectomy)
- Level of confidence in the evidence: Medium, because of limited data on long-term benefits of these interventions and heterogeneity among RCTs included in the systematic reviews
- Benefit: Promoting effective therapy; avoiding adenoidectomy in an age group where benefits have not been shown as a primary intervention for OME; benefits of surgery that include improved hearing reduced prevalence of OME, and less need for additional tympanostomy tube insertion (after adenoidectomy)
- Risks, harms, costs: Risks of anesthesia and specific surgical procedures, sequelae of tympanostomy tubes and adenoidectomy
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Although some studies suggest benefits of adenoidectomy for children <4 years old as primary therapy for OME, the data are inconsistent and relatively sparse; the additional surgical risks of adenoidectomy (e.g., velopharyngeal insufficiency, more complex anesthesia) were felt to outweigh the uncertain benefits in this group
- Intentional vagueness: For children aged ≥4 years, the decision to offer tympanostomy tubes, adenoidectomy, or both is based on shared decision making
- Role of patient preferences: Moderate role in the choice of surgical procedure for children aged ≥4 years (tubes, adenoidectomy, or both)
- Exceptions: Adenoidectomy may be contraindicated in children with cleft palate or syndromes associated with a risk of velopharyngeal insufficiency
- Policy level: Recommendation
- Difference of opinion: None

Statement 13. Outcome Assessment

When managing a child with OME, clinicians should document in the medical record resolution of OME, improved hearing, or improved quality of life.

Recommendation based on randomized trials and cohort studies with a preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: Focus on patient-centered outcome assessment when managing children with OME (National Quality Strategy domain: clinical process/effectiveness)
- Aggregate evidence quality: Grade C, randomized trials and before-and-after studies showing resolution, improved hearing, or improved quality of life after management of OME
- Level of confidence in the evidence: High
- Benefit: Document favorable outcomes in management
- Risks, harms, costs: Cost of follow-up visits and audiometry; administrative burden for quality of life surveys
- Benefit-harm assessment: Predominance of benefit over harm
- Value judgments: None
- Intentional vagueness: The time frame for assessing outcome is not stated; the method of demonstrating OME resolution (otoscopy or tympanometry) is at the discretion of the clinician
- Role of patient preferences: Small
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

Definitions

Aggregate Grades of Evidence by Question Type

Grade	Treatment	Diagnosis	Prognosis
A	Systematic review[a] of randomized trials	Systematic review[a] of cross-sectional studies with consistently applied reference standard and blinding	Systematic review[a] of inception cohort studies[b]
B	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Cross-sectional studies with consistently applied reference standard and blinding	Inception cohort studies[b]
C	Nonrandomized or historically controlled studies, including case-control and observational studies	Nonconsecutive studies, case-control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Cohort study, control arm of a randomized trial, case series, or case-control studies; poor-quality prognostic cohort study
D	Case reports, mechanism-based reasoning, or reasoning from first principles		
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm		

[a]A systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.

[b]A group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition or before the condition develops.

Strength of Action Terms in Guideline Statements and Implied Levels of Obligation

Strength	Definition[a]	Implied Obligation
Strong Recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or, in the case of a strong negative recommendation, that the harms clearly exceed the benefits) and that the quality of the supporting evidence is high (Grade A or B). In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.

Recommendation Strength	Definition[a]	Implied Obligation
	A recommendation means the benefits exceed the harms (or, in the case of a negative recommendation, that the harms exceed the benefits), but the quality of evidence is not as high (Grade B or C). In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive or patient preferences.
Option	An option means that either the quality of evidence is suspect (Grade D) or that well-done studies (Grade A, B, or C) show little clear advantage to one approach vs another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.

[a]See the "Rating Scheme for the Strength of Evidence" field for definitions of evidence grades.

Clinical Algorithm(s)

An algorithm titled "Algorithm Showing the Relationship of Guideline Key Action Statements" is provided in the original guideline document.

Scope

Disease/Condition(s)

Otitis media with effusion (OME)

Guideline Category

Diagnosis

Evaluation

Management

Risk Assessment

Clinical Specialty

Family Practice

Nursing

Otolaryngology

Pediatrics

Speech-Language Pathology

Surgery

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Speech-Language Pathologists

Guideline Objective(s)

- To provide evidence-based recommendations to manage otitis media with effusion (OME), defined as the presence of fluid in the middle ear without signs or symptoms of acute ear infection
- To identify quality improvement opportunities in managing OME and to create explicit and actionable recommendations to implement these opportunities in clinical practice

Target Population

Children aged 2 months through 12 years with otitis media with effusion (OME), with or without developmental disabilities or underlying conditions that predispose to OME and its sequelae

Note: This guideline does not apply to patients <2 months or >12 years old.

Interventions and Practices Considered

Diagnosis/Evaluation

1. Pneumatic otoscopy
2. Tympanometry
3. Routine screening (considered but recommended against)
4. Identification of the child with otitis media with effusion (OME) at risk for speech, language, or learning problems and evaluating hearing, speech, language, and need for intervention more promptly

Management

1. Watchful waiting in children with OME who are not at risk
2. Antihistamines, decongestants, antimicrobials, and corticosteroids (considered but strongly recommended against)
3. Hearing testing as needed
4. Surveillance of chronic OME at 3- to 6-month intervals
5. Counseling of parents
    - Infants with OME who fail a newborn hearing screen
    - Natural history of OME, need for follow-up, and possible sequelae
    - Potential impact of OME on speech and language
6. Referral to a specialist
7. Surgery as appropriate, including tympanostomy tube insertion, adenoidectomy
8. Documentation of outcomes (resolution of OME, improved hearing, improved quality of life)

Major Outcomes Considered

- Sensitivity, specificity, and predictive values of diagnostic tests
- Hearing loss
- Effects of otitis media with effusion (OME) on speech, language, and learning
- Physiologic sequelae of OME
- Health care utilization (medical, surgical)

- Functional health status
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search

An information specialist conducted 2 systematic literature searches using a validated filter strategy to identify clinical practice guidelines, systematic reviews, and randomized controlled trials (RCTs) published since the prior guideline (2004). Search terms used were "Otitis Media with Effusion" [Mesh] OR "otitis media with effusion"[tiab] OR (OME[tiab] AND otitis) OR "middle ear effusion"[tiab] OR "glue ear"[tiab]; otitis/exp OR otitis AND media AND (effusion/exp OR effusion); MH "Otitis Media with Effusion" OR TI (OME and effusion) OR TI "otitis media with effusion"; and (DE "OTITIS MEDIA") OR "otitis media with effusion" OR (OME AND otitis) OR "middle ear effusion" OR "glue ear." In certain instances, targeted searches for lower-level evidence were performed to address gaps from the systematic searches identified in writing the guideline. The original MEDLINE search was updated from January 2004 to January 2015 to include Medline, National Guideline Clearinghouse, Cochrane Database of Systematic Reviews, Excerpta Medica database, Cumulative Index to Nursing and Allied Health, and the Allied and Complimentary Medicine Database.

Number of Source Documents

1. The initial search for clinical practice guidelines identified 13 guidelines. Quality criteria for including guidelines were (a) an explicit scope and purpose, (b) multidisciplinary stakeholder involvement, (c) systematic literature review, (d) explicit system for ranking evidence, and (e) explicit system for linking evidence to recommendations. The final data set retained 4 guidelines that met inclusion criteria.
2. The initial search for systematic reviews identified 138 systematic reviews or meta-analyses that were distributed to the panel members. Quality criteria for including reviews were (a) relevance to the guideline topic, (b) clear objective and methodology, (c) explicit search strategy, and (d) valid data extraction methods. The final data set retained was 20 systematic reviews or meta-analyses that met inclusion criteria.
3. The initial search for randomized controlled trials (RCT) identified 86 RCTs that were distributed to panel members for review. Quality criteria for including RCTs were (a) relevance to the guideline topic, (b) publication in a peer-reviewed journal, and (c) clear methodology with randomized allocation to treatment groups. The total final data set retained 49 RCTs that met inclusion criteria.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Aggregate Grades of Evidence by Question Type

Grade	Treatment	Diagnosis	Prognosis
A	Systematic review[a] of randomized trials	Systematic review[a] of cross-sectional studies with consistently applied reference standard and blinding	Systematic review[a] of inception cohort studies[b]
B	Randomized trials or observational	Cross-sectional studies with consistently	Inception cohort studies[b]

Grade	Treatment	Diagnosis	Prognosis
	Studies with dramatic effects or highly consistent evidence	Applied reference standard and blinding	
C	Nonrandomized or historically controlled studies, including case-control and observational studies	Nonconsecutive studies, case-control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Cohort study, control arm of a randomized trial, case series, or case-control studies; poor-quality prognostic cohort study
D	Case reports, mechanism-based reasoning, or reasoning from first principles		
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm		

[a]A systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.

[b]A group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition or before the condition develops.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the quality of evidence and the balance of benefit and harm that is anticipated when the statement is followed. The definitions for evidence-based statements are listed in the "Rating Scheme for the Strength of Evidence" and "Rating Scheme for the Strength of the Recommendations" fields.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

In developing this update of the evidence-based clinical practice guideline, the methods outlined in the third edition of the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) guideline development manual (see the "Availability of Companion Documents" field) were followed explicitly.

The AAO-HNSF assembled a guideline update group (GUG) representing the disciplines of otolaryngology–head and neck surgery, pediatric otolaryngology, otology, pediatrics, allergy and immunology, family medicine, audiology, speech-language pathology, advanced practice nursing, and consumer advocacy. The GUG had several conference calls and one in-person meeting during which it defined the scope and objectives of updating the guideline, reviewed comments from the expert panel review for each key action statement, identified other quality improvement opportunities, and reviewed the literature search results.

The evidence profile for each statement in the earlier guideline was then converted into an expanded action statement profile for consistency with the AAO-HNSF's current development standards. Information was added to the action statement profiles regarding the quality improvement opportunity, level of confidence in the evidence, differences of opinion, intentional vagueness, and any exclusion to which the action statement does not apply. New key action statements were developed with an explicit and transparent *a priori* protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm. Electronic decision support software (BRIDGE-Wiz; Yale Center for Medical Informatics, New Haven, Connecticut) was used to facilitate creating actionable recommendations and evidence profiles.

The updated guideline underwent GuideLine Implementability Appraisal to appraise adherence to methodologic standards, improve clarity of recommendations, and predict potential obstacles to implementation. The GUG received summary appraisals and modified an advanced draft of

the guideline based on the appraisal.

Rating Scheme for the Strength of the Recommendations

Strength of Action Terms in Guideline Statements and Implied Levels of Obligation

Strength	Definition[a]	Implied Obligation
Strong Recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or, in the case of a strong negative recommendation, that the harms clearly exceed the benefits) and that the quality of the supporting evidence is high (Grade A or B). In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means the benefits exceed the harms (or, in the case of a negative recommendation, that the harms exceed the benefits), but the quality of evidence is not as high (Grade B or C). In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive or patient preferences.
Option	An option means that either the quality of evidence is suspect (Grade D) or that well-done studies (Grade A, B, or C) show little clear advantage to one approach vs another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.

[a]See the "Rating Scheme for the Strength of Evidence" field for definitions of evidence grades.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The final draft of the updated clinical practice guideline was revised based on comments received during multidisciplinary peer review, open public comment, and journal editorial peer review.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Improved diagnostic accuracy of otitis media with effusion (OME); more prompt diagnosis of sensorineural hearing loss (SNHL); and earlier intervention for hearing loss

For benefits of specific interventions considered in the guideline, see the "Major Recommendations" field.

Potential Harms

The most common tube-related sequela of tympanostomy tubes is otorrhea, which is seen in approximately 16% of children within 4 weeks of surgery and 26% of children at any time the tube remains in place (mean, 12-14 months). Complications of tympanostomy tubes include an obstructed tube lumen in 7% of intubated ears, premature extrusion of the tube in 4%, and tube displacement into the middle ear in 0.5%.

For possible harms of specific interventions considered in the guideline, see the "Major Recommendations" field.

Contraindications

Contraindications

Adenoidectomy may be contraindicated in children with cleft palate or syndromes associated with a risk of velopharyngeal insufficiency.

Qualifying Statements

Qualifying Statements

- The clinical practice guideline is provided for information and educational purposes only. It is not intended as a sole source of guidance in managing otitis media with effusion (OME). Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to diagnosing and managing this program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions but are not absolute. Guidelines are not mandates; these do not and should not purport to be a legal standard of care. The responsible provider, in light of all circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.
- Guidelines are never intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a strong recommendation than what might be expected with a recommendation. Options offer the most opportunity for practice variability. Clinicians should always act and decide in a way that they believe will best serve their individual patients' interests and needs, regardless of guideline recommendations. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.
- Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the guideline update group (GUG) sought to minimize harm, diminish unnecessary and inappropriate therapy, and reduce the unnecessary use of systemic antibiotics. A major goal of the panel was to be transparent and explicit about how values were applied and to document the process.

Implementation of the Guideline

Description of Implementation Strategy

Implementation Considerations

The complete guideline is published as a supplement to *Otolaryngology–Head and Neck Surgery*, and an executive summary will be simultaneously published in the main journal. A full-text version of the guideline will also be accessible free of charge at www.entnet.org, the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) Web site. The guideline will be presented to AAO-HNSF members as a mini-seminar at the 2015 annual meeting. Existing brochures, publications, and patient information sheets from the AAO-HNSF will be updated to reflect guideline recommendations.

Although pneumatic otoscopy and tympanometry were recommended for diagnosing otitis media with effusion (OME) in the first version of this guideline, pneumatic otoscopy in particular continues to be underused in primary care settings. The guideline update group (GUG) provides expanded information on both these diagnostic modalities in the new guideline, but enhanced efforts will still be needed in primary care settings to teach and promote accurate OME diagnosis. The degree to which specialists use pneumatic otoscopy has not been studied, but educational efforts would likely be of benefit to this population as well.

OME is one of the most common reasons that infants fail a newborn hearing test, but ensuring follow-up to assess for resolution of the effusion and to exclude an underlying sensorineural hearing loss (SNHL) can be challenging. AAO-HNSF provides counseling materials in this regard that clinicians can distribute to families of children with OME, but continued education of hospital providers who administer the newborn testing is an additional challenge. The GUG hopes that the new attention focused on this issue by the guideline will promote investigation and change in this area.

The new guideline reaffirms a prior recommendation against routine screening of children for OME but adds a new recommendation that clinicians evaluate at-risk children for OME when the at-risk condition is diagnosed and again at 12 to 18 months of age (if diagnosed as being at risk prior to this time). This new recommendation imposes some additional burden on providers, in terms of both remembering to do the assessment and performing the actual evaluation for OME. The GUG showed strong consensus and support for this recommendation as a means to improve quality of care for at-risk children. Implementing this in practice will require continuing medical education strategies and integration into clinical decision support systems.

Whereas antibiotics and oral steroids are used infrequently to treat OME, there is a perception that topical intranasal steroids and antireflux medications are relatively common interventions, despite a lack of evidence for their efficacy. The GUG recommends explicitly against using these for a primary indication of OME, but reinforcement will be needed to implement this strategy, especially through performance measures. This is especially important to avoid costly, ineffective, and potentially harmful care.

Last, the GUG makes a new recommendation that adenoidectomy should not be done for a primary indication of OME in children <4 years old. This contradicts established practice for many clinicians and some information in the prior guideline (e.g., offering adenoidectomy when repeat surgery is required for children ≥2 years old). Continuing medical education will be needed to explicitly focus on the rationale for this change (e.g., new randomized trials and systematic reviews) to promote uptake in routine clinical practice.

Implementation Tools

Clinical Algorithm

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Quick Reference Guides/Physician Guides

Resources

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Rosenfeld RM, Shin JJ, Schwartz SR, Coggins R, Gagnon L, Hackell JM, Hoelting D, Hunter LL, Kummer AW, Payne SC, Poe DS, Veling M, Vila PM, Walsh SA, Corrigan MD. Clinical practice guideline: otitis media with effusion (update). Otolaryngol Head Neck Surg. 2016 Feb;154(1 Suppl):S1-S41. [212 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2016 Feb

Guideline Developer(s)

American Academy of Otolaryngology - Head and Neck Surgery Foundation - Medical Specialty Society

Source(s) of Funding

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF).

Guideline Committee

American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) Guideline Update Group (GUG)

Composition of Group That Authored the Guideline

Panel Members: Richard M. Rosenfeld, MD, MPH, Department of Otolaryngology, SUNY Downstate Medical Center, Brooklyn, New York, USA; Jennifer J. Shin, MD, SM, Division of Otolaryngology, Harvard Medical School, Boston, Massachusetts, USA; Seth R. Schwartz, MD, MPH, Department of Otolaryngology, Virginia Mason Medical Center, Seattle, Washington, USA; Robyn Coggins, MFA, Society for Middle Ear Disease, Pittsburgh, Pennsylvania, USA; Lisa Gagnon, MSN, CPNP, Connecticut Pediatric Otolaryngology, Madison, Connecticut, USA; Jesse M. Hackell, MD, Pomona Pediatrics, Pomona, New York, USA; David Hoelting, MD, American Academy of Family Physicians, Pender, Nebraska, USA; Lisa L. Hunter, PhD, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, USA; Ann W. Kummer, PhD, CCC-SLP, University of Virginia Health System, Charlottesville, Virginia, USA; Spencer C. Payne, MD, University of Virginia Health System, Charlottesville, Virginia, USA; Dennis S. Poe, MD, PhD, Department of Otology and Laryngology, Harvard Medical School and Boston Children's Hospital, Boston, Massachusetts, USA; Maria Veling, MD, University of Texas–Southwestern Medical Center/Children's Medical Center–Dallas, Dallas, Texas, USA; Peter M. Vila, MD, MSPH, Department of Otolaryngology–Head and Neck Surgery, Washington University School of Medicine in St Louis, St Louis, Missouri, USA; Sandra A. Walsh, Consumers United for Evidence-Based Healthcare, Davis, California, USA; Maureen D. Corrigan, American Academy of Otolaryngology—Head and Neck Surgery Foundation, Alexandria, Virginia, USA

Financial Disclosures/Conflicts of Interest

Financial Disclosure and Conflicts of Interest

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF). Potential conflicts of interest for all panel members in the past 5 years were compiled and distributed before the first conference call and were updated at each subsequent call and in-person meeting. After review and discussion of these disclosures, the panel concluded that individuals with potential conflicts could remain on the panel if they (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed to not discuss any aspect of the guideline with industry before publication. Last, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, how a participant earns a living, and the participant's previously established "stake" in an issue.

Disclosures

Competing Interests: Jennifer J. Shin, royalties from the publication of 2 books—*Evidence-Based Otolaryngology* (Springer International), *Otolaryngology Prep and Practice* (Plural Publishing)—and recipient of a Harvard Medical School Shore Foundation Faculty Grant; Lisa L. Hunter, teaching/speaking honoraria from Interacoustics Inc and Arizona Ear Foundation, research funding from National Institute on Deafness and Other Communication Disorders and Centers for Disease Control and Prevention, textbook royalties from Plural Publishing (Acoustic Immittance Measures); Ann W. Kummer, textbook royalties from Engage Learning (*Cleft Palate and Craniofacial Anomalies*); Spencer C. Payne, consulting fee from Acclarent, Medtronic, Styker, and Cook; research funding from Acclarent; expert witness (case-by-case basis); Dennis S. Poe, research funding from Acclarent for eustachian tube dilation balloons, financial interest in nasal spray for otitis media (not yet in phase I trials); Stockholder–Otodyne; Maureen D. Corrigan, salaried employee of the AAO-HNSF.

Guideline Endorser(s)

American Academy of Family Physicians - Medical Specialty Society

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Academy of Family Physicians, American Academy of Otolaryngology-Head and Neck Surgery, American Academy of Pediatrics Subcommittee on Otitis Media with Effusion. Otitis media with effusion. Pediatrics. 2004 May;113(5):1412-29. [172 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the SAGE Journals Web site.

Availability of Companion Documents

The following are available:

- Rosenfeld RM, Shin JJ, Schwartz SR, Coggins R, Gagnon L, Hackell JM, Hoelting D, Hunter LL, Kummer AW, Payne SC, Poe DS, Veling M, Vila PM, Walsh SA, Corrigan MD. Clinical practice guideline: otitis media with effusion executive summary (update). Otolaryngol Head Neck Surg. 2016 Feb;154(2):201-14. Available from the SAGE Journals Web site.
- Clinical practice guideline: otitis media with effusion (update). Podcast part 1 and 2. Alexandria (VA): American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF). 2016 Feb. Available from the American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF) Web site.
- Clinical practice guideline: otitis media with effusion (update). Pocket guide and mobile app. Alexandria (VA): American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF). 2016 Feb. Available from the AAO-HNSF Web site.
- Rosenfeld RM, Shiffman RN, Robertson P. Clinical practice guideline development manual, third edition: a quality-driven approach for translating evidence into action. Otolaryngol Head Neck Surg. 2013 Jan;148(Suppl 1):S1-55. Electronic copies: Available from the SAGE Journals Web site.

In addition, a slideset is available from the AAO-HNSF by contacting Sarah O'Connor (soconnor@entnet.org).

Patient Resources

A variety of resources for parents are available from the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) Web site.

NGC Status

This NGC summary was completed by ECRI on July 2, 2004. The information was verified by the guideline developer on August 4, 2004. This summary was updated by ECRI Institute on May 2, 2016. The updated information was verified by the guideline developer on June 22, 2016.

Copyright Statement

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouseâ„¢ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional

associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion-criteria.aspx.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.